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**Prescription Monitoring and Drug Control Program Advisory**

**TO:** Licensed Prescribers and Dispensers

**FROM:** Deborah Allwes, Director, Bureau of Health Care Safety and Quality

**DATE:** November 20, 2014

**RE:** Final promulgation of Amendments to 105 CMR 700.000 (Implementation of M.G.L. c. 94C Controlled Substances Act) Related to Use of the Prescription Monitoring Program and to 105 CMR 721.000 (Standards for Approved Prescription Forms in Massachusetts)

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**Introduction**

The purpose of this advisory is to announce the final promulgation by the Public Health Council (PHC) on November 12, 2014, of the amendments to 105 CMR 700.000, related to the use of the Prescription Monitoring Program, and 105 CMR 721.000, Standards for Approved Prescription Forms in Massachusetts. The regulations will take effect upon publication by the Secretary of State. The expected publication date is December 5, 2014.

These amendments to regulations serve three purposes, to: (1) enhance utilization of the Massachusetts Prescription Monitoring Program (PMP) that provides prescribers and dispensers with additional information that can inform clinical decision making; (2) permit prescribers to prescribe naloxone to a person other than the ultimate user; and (3) be consistent with new rules regarding prescriptions issued by physician assistants. In addition, these amendments include some technical changes to reflect changes made to other Department regulations.

**Requirements**

The new proposed amendments fulfill the statutory mandates of Chapter 244 of the Acts of 2012 and Chapter 38 of the Acts of 2013. The amendments regarding prescriptions issued by physician assistants are authorized by Chapter 224 of the Acts of 2012.

Specifically the changes will improve public health and safety by:

- requiring certain PMP participants to utilize the PMP prior to issuing to a patient, for the first time, a prescription for a Schedule II or III narcotic drug, or for a drug product containing a benzodiazepine;
- outlining those times when a registered individual prescriber does not have to utilize the PMP, such as during emergency care, or other identified circumstances;
- enabling the Department to issue guidance on PMP utilization prior to prescribing commonly abused and addictive prescription drug products in Schedules IV and V;

- allowing for the use of delegates, a class of PMP users who, as authorized support staff, may use the system (as designated by the Department) on behalf of a registered participant; and
- creating a process by which access to the MA Online PMP may be suspended or revoked if a user violates the terms and conditions for use of the system.

The Governor declared a public health emergency in March 2014, in response to the opioid epidemic. Therefore these amendments include an additional requirement that all prescribers utilize the PMP each time they issue a prescription for a drug in Schedule II or III which has been determined to be commonly misused or abused and needs additional safeguards. The regulations direct the Department to set up an advisory group to make such determinations and recommendations. Any prescription drug that is added in an amendment to this regulation will be approved by the Department and go through the regulatory process. This provision will ensure that the PMP can be used to ensure safe prescribing and dispensing for prescription drugs that are subject to abuse and misuse and require additional safeguards.

To better articulate the process by which a Massachusetts Controlled Substance registration may be suspended or revoked, the amendments include sections related to administrative procedure so that registrants can understand the investigation and appeals process.

The automatic enrollment of physicians, dentists and podiatrists began in January, 2013 and is still continuing. The process to automatically enroll prescribing advance practice registered nurses and physician assistants will begin in January, 2015. Automatic enrollment for all prescribers will continue simultaneously with the renewal of their Massachusetts Controlled Substance Registration.

By mid-December the policies and procedures regarding delegates (including using delegates and how a delegate is registered or unregistered) will be posted on the MA Online PMP website (<http://www.mass.gov/dph/dcp/onlinepmp>) and on the MA Online PMP splash page under new information. Additionally, PMP on-line video tutorials, quick reference pamphlets and other materials will be available for download. Information will be sent to all prescribers and dispensers on how and where to access this information.

To view the PHC regulations, please visit <http://www.mass.gov/eohhs/gov/laws-regs/dph/proposed-regulations/prescription-monitoring-program.html>. Final regulations will be posted on the Prescription Monitoring and Drug Control website, <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/>, once available from the Secretary of State.

The Department looks forward to working hand-in-hand with prescribers to ensure compliance with these laws and regulations. As mandatory enrollment proceeds, we look forward to receiving your questions and concerns, as well as making important improvements to this process to ensure greater ease of use, and ultimately, greater patient safety.

For immediate questions, please contact:

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